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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,135	02/05/2002	David Wayne Schroeder	5490-000220	7517
27572	7590	05/11/2004	EXAMINER	
HARNESS, DICKEY & PIERCE, P.L.C. P.O. BOX 828 BLOOMFIELD HILLS, MI 48303			RAMANA, ANURADHA	
			ART UNIT	PAPER NUMBER
			3732	

DATE MAILED: 05/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,135	SCHROEDER, DAVID WAYNE	
	Examiner	Art Unit	
	Anu Ramana	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 February 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-5,8-14,17-22,24-25 and 28-30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-5,8-14,17-22,24,25 and 28-30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-14, 17-19, 21-22, 24-25 and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. (US 5,879,404) in view of Asthana et al. (US 2003/0175488), and Shelley (JP402161943).

Bateman et al. disclose a composite acetabular component having a ceramic bearing liner or "insert member" 2 and an outer shell or "backing member" 3 wherein the outer shell is made of a thermoplastic material such as polymethylmethacrylate, polyethylene or ultra-high molecular weight polyethylene (col. 1, lines 30-39, col. 2, lines 43-47, lines 66-67 and col. 3, lines 1-4).

Bateman et al. further disclose a method of making a composite acetabular component having the steps of: providing a ceramic insert member 2; providing a thermoplastic material; softening the thermoplastic material (e.g. injection or compression molding (col. 4, lines 37-41); and contacting the outer surface of the ceramic insert member 2 with the softened thermoplastic material to form backing member 3 around insert 2 (col. 4, lines 27-33 and lines 37-41).

Bateman et al. do not disclose that the outer surface of ceramic insert 2 is provided with texture and radially disposed macro-grooves.

Asthana et al. teach that adhesion between a polymer layer and an underlying substrate or ceramic layer is enhanced by providing a texture to the surface of the ceramic layer (para [0006], lines 11-14, para [0028] and para [0129]-[0132]).

Accordingly it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the composite acetabular component of Bateman et al. with the outer surface of insert member 2 having a texture, in view of Asthana et al., in order to enhance adhesion of insert 2 with backing member 3.

Shelley teaches a composite acetabular component having an outer shell or cup and a plastic insert 9 wherein radial grooves 16 are provided on the inner surface of the cup to prevent rotation of insert 9 within the cup. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided radial grooves 16 on the ceramic bearing insert 2 of the acetabular component of the combination of Bateman et al. and Asthana et al., to prevent rotation of bearing insert within the outer shell, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 7.

With regard to claims 4-5 and 13-14 it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the composite acetabular component of the combination of Bateman et al. and Asthana et al., as modified by Shelley with a texture or "roughened surface" having an arithmetic mean roughness in a range of about 5 to about 10 microns or a ten-point mean roughness in a range of about 50 to about 75 microns since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 8, the Applicant has failed to establish the criticality of the macro-grooves having a longitudinal orientation with respect to the hemispherical surface of the insert. It is the Examiner's opinion that any orientation could be used and thus the device of the combination of Bateman et al., Asthana et al. and Shelley would perform equally well as the claimed invention.

With regard to claim 19, Bateman discloses an acetabulum replacement system including an acetabulum member 12 and a composite acetabular component having a ceramic insert member 11 and a thermoplastic backing member 13 wherein the composite acetabular component is secured or molded to the acetabulum member 12 (Figure 5 and col. 5, lines 41-48). Accordingly, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to construct the acetabulum replacement system of Bateman et al. with the outer surface of insert member 11 having a texture, in view of Asthana et al., to enhance adhesion of insert 11 with backing member 13, and radially positioned macro-grooves, in view of Shelley, in order to prevent rotation of insert 11 in backing member 13.

Art Unit: 3732

With regard to the method steps of claims 21-22 and 28-30, the step of imparting a texture to the outer surface of ceramic insert member 2 and contacting the textured outer surface of ceramic insert member 2 with the softened thermoplastic material, it is noted that these steps are inherent in the combination of Bateman et al., Asthana et al. and Shelley.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bateman et al. in view of Asthana et al. and Shelley, further in view of Sherman (US 4,936,855).

Sherman teaches a conventional hip replacement system as having an acetabulum-type cup member and a spherical head member which mates with and is rotatably supported by the spherical cavity of the cup member for articulated motion associated with the hip joint (col. 1, lines 46-58).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to construct a hip replacement system as taught by Sherman wherein the acetabulum-type cup member is the acetabulum replacement system of the combination of Bateman et al., Asthana et al. and Shelley (see previous discussion for claim 1) wherein so doing would amount to mere substitution of one functionally equivalent structure for another within the same art and the selection of any of these structures would work equally well in a conventional hip replacement system.

Response to Arguments

Applicant's arguments with respect to claims 1, 11, 19 and 21, submitted under "REMARKS" in the response filed on February 23, 2004, have been considered but are not persuasive.

Regarding Applicant's arguments that there is no teaching or motivation in the cited art to combine Bateman et al. with Asthana et al. and Shelley to render obvious claims 1, 11, 19 and 21, it is the Examiner's position that there is motivation to combine Bateman et al., Asthana et al. and Shelley.

Bateman et al. disclose an acetabular implant or article constructed with a polymer layer attached to a ceramic layer and Asthana et al. teach improving adhesion between a polymer layer and an underlying ceramic layer in a multi-layered article by modifying the surface of at least one of the layers with a mechanical texture or "microroughness." Shelley teaches providing

radial grooves (16) in a surface to prevent rotation of the surface when placed in contact with another surface (see Figure 3).

A prior art reference is analogous if the reference is in the field of the Applicant's endeavor or, if not, is reasonably pertinent to the particular problem with which the inventor was concerned (see MPEP 2145). Asthana et al. is reasonably pertinent to the particular problem with which the inventor was concerned, namely adhesion between two layers. *In re Oetiker*, 977, F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

Regarding Applicant's arguments with respect to Shelley, it is the Examiner's position that Shelley teaches a plastic insert or liner that is mechanically bonded to a shell by plastic flowing from the insert into a groove in the shell and wherein additional radial grooves are provided on the surface of the shell to prevent rotation of the insert after it is fitted into the shell. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided radial grooves on the insert surface instead of the shell surface, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 7.

The inventions of references need not be physically combinable to render obvious an applicant's invention. *In re Sneed*, 710 F. 2d 1544, 218 USPQ 385, 389 (Fed. Cir. 1983). The test for obviousness is not whether the features of a reference may be bodily incorporated into the structure of another reference but rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. *In re Keller*, 642 F.2d 413 208 USPQ 871 (CCPA 1981). In the instant case, Asthana et al. and Shelley teach that providing a texture and grooves on the surface of a layer ensures that the layer adheres to or mates with another layer in a multi-layered article, a concept that can be utilized in constructing a multi-layered article, such as a composite acetabular component, as disclosed by Bateman et al.

Regarding claim 20, the Applicant has not disclosed the criticality of providing a longitudinal orientation to the macrogrooves. One of ordinary skill in the art would have expected Applicant's invention to perform equally well with radially oriented macrogrooves because Shelley teaches radially oriented grooves or "macrogrooves" 16 to prevent relative rotation between an insert or "liner" and a cup.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Anu Ramana*
May 5, 2004



EDUARDO C. ROBERT
PRIMARY EXAMINER